OFFICE OF THE DEPARTMENT OF DEFENSE COORDINATOR
FOR DRUG ENFORCEMENT POLICY AND SUPPORT

1510 DEFENSE PENTAGON
WASHINGTON DC 20301-1510

14 OCT 1997

MEMORANDUM FOR ASSISTANT SECRETARY OF THE NAVY (ATTN: N313)
DEPUTY ASSISTANT SECRETARY OF THE ARMY FOR MILITARY PERSONNEL MANAGEMENT AND EQUAL OPPORTUNITY POLICY
DEPUTY ASSISTANT SECRETARY OF THE AIR FORCE FOR FORCE MANAGEMENT AND PERSONNEL

SUBJECT: Amphetamine/Methamphetamine Screening in Department of Defense Drug Testing Laboratories

Attached is a copy of the memorandum from the Food and Drug Administration (FDA) granting Roche Diagnostics Systems clearance for the use of periodate in the Abuscreen On-Line^{R} reagent system for amphetamine and methamphetamine analysis. Therefore, my memorandum of October 22, 1996 is rescinded. Periodate may now be added to the microparticle beads for amphetamine and methamphetamine analyses conducted under Department of Defense Demand Reduction military drug testing program.

It is recommended that 600 microliters (uL) of 0.4M periodate be added per 15 ml of R2 microbead reagent volume. For additional information regarding the use of periodate, please contact your Service Technical Drug Program Manager or Captain John F. Jemionek, MSC, USN, at (703) 693-1917 or DSN 223-1917. Your continued support of the DoD Demand Reduction Program is appreciated.

for Robert J. Newberry
Principal Director for
Drug Enforcement Policy and Support

Attachment:
As stated

CF:
Army MEDCOM, ATTN: LTC Jacobs, MS, USA
NEHC, ATTN: CDR Past, MSC, USN
Air Force OSG, ATTN: LtCol Litts, USAF, MC
FTDTL Fort Meade, ATTN: LTC Armitage, MS, USA
FTDTL Tripler AMC, ATTN: MAJ Lukey, MS, USA
NDSL Jacksonville, ATTN: LCDR McWhorter, MSC, USN
NDSL Great Lakes, ATTN: CDR Lininger, MSC, USN
NDSL San Diego, ATTN: LCDR Vias, MSC, USN
Brooks AFB Drug Laboratory, ATTN: LtCol Swaby, USAF, BSC
NWT Laboratories Inc., Salt Lake City, UT, ATTN: Dr. Smith, Ph.D.

Memo

Roche

Diagnostics

To:	Distribution	
Copies:		
From:	James Haynes Regulatory Affairs Associate	Bldg. 500 Tel. (908) 253-7569 Fax (908) 253-7547
Date:	October 7, 1997	
Subject:	Abuscreen ONLINE for Amphetamines with Periodate-Olympus AU800/1000 Application	

The Abuscreen OnLine for Amphetamines with Periodate - Olympus AU800/1000 Application was cleared by the FDA on October 1, 1997. The use of Periodate with the Abuscreen OnLine for Amphetamines minimizes interference which may be caused by the presence of over-the-counter products in the urine samples. This application will be used primarily by the Department of Defense. Approximate review time at FDA was 10 weeks. Attached please find a copy of the clearance letter along with the Indication for Use sheet.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 1 1997

James W. Haynes
Regulatory Affairs Associate
Roche Diagnostics Systems
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K972891
Abuscreen ONLINE for Amphetamines with Periodate
Olumpus AU800/1000
Product Code: DKZ
Regulatory Class: II
Dated: August 4, 1997
Received: August 5, 1997

Dear Mr. Haynes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) 97289 |

Device Name: Abuscreen ONLINE for Amphetamines with Periodate Olympus AU800/1000 Instrument Application

Indications for Use:

The Abuscreen ONLINE for Amphetamines is an in vitro diagnostic test for the qualitative and semi-quantitative detection of amphetamine and methamphetamine and their metabolites in human urine. Periodate may be used in conjunction with Abuscreen ONLINE for Amphetamines to minimize interference which may be caused by the presence of β-hydroxamine compounds in urine samples.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K97289

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)